Title: Wireless Internet Bio-telemetry Monitoring System and Method

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Related Applications:

This application is a continuation-in-part of U.S. Application Serial No. 09/516,645, filed March 1, 2000, now pending.

Field of the Invention:

This invention relates generally to medical monitoring devices. More particularly the present invention is a system and method for monitoring physiologic variables of an individual in a wireless manner over the Internet.

Background of the Invention:

Monitoring devices of various types to monitor patient physiologic conditions have long been in the medical community. A plethora of testing and monitoring equipment have moved out of the hospital into the doctors' offices and, in some cases, have even progressed into home monitoring systems.

While these devices have clearly been extremely useful, many of these devices require that a patient be located at home, or in close proximity to a telephone system, such that results of the monitoring can be transmitted over the public switched telephone network (PSTN) to some form of analysis center. Such devices do not necessarily lend themselves to the mobile life style in which many individuals find themselves.

For example, it is difficult for a busy person to stop in the middle of the day, proceed to a monitoring station (whether it be at home or in some office) take the appropriate measurements,

and then proceed with the business of the day. This simply is not possible and adds a level of stress to the already stressful situation of having to monitor physiologic signals.

What would truly be useful is a system for monitoring physiologic characteristics of an individual on a mobile basis. Such a system would require little if any interaction with a monitoring device. Signals that are collected would then be sent in an automated fashion to an analysis center or a physician's office. Alternatively, a physician could interrogate the system worn by a patient while the patient is mobile to obtain the physiologic signals of interest.

Summary of the Invention:

It is therefore an objective of the present invention to monitor remotely the physiologic variables from any patient.

It is a further objective of the present invention to monitor physiologic variables of a patient (regardless of whether the patient is ambulatory or stationary) when the physician is remote from the patient.

It is yet another objective of the present invention to monitor physiologic variables using the Internet.

It is a further objective of the present invention to monitor physiologic variables in a wireless manner within a generalized geographic area.

It is a further objective of the present invention to monitor physiologic variables without the patient having to proceed to any centralized location in a geographic area.

It is a further objective of the present invention to monitor a patient anywhere in the coverage map of a cellular- or satellite-based telephone network.

It is a further objective of the present invention to have data relating to physiologic

variables automatically sent over a wireless network to a physician or other medical caregiver using the Internet.

It is a further objective of the present invention to allow a physician to interrogate the physiologic monitoring device in a wireless fashion whenever the physician needs to take such physiologic measurements.

It is a further objective of the present invention to provide voice communications in a wireless mode to and from a medical caregiver.

It is a further objective of the present invention to have a "panic" function which allows both a user to send a panic message to a physician or allows a physician, after monitoring physiologic signals, to send a voice "advice" message to the patient.

It is a further objective of the present invention to accomplish all the above objectives using a device that is worn by the patient in a relatively unobtrusive fashion.

These and other objectives of the present invention will become apparent to those skilled in the art from a review of the specification that follows. The words physician, doctor, healthcare provider, caregiver, medical care provider, care provider, etc. as used herein shall mean the person with responsibility for the care of the patient.

The present invention is a wireless Internet bio-telemetry monitoring system (WIBMS). The system makes use of a variety of bio-sensors which are generally used to detect signals or variables from the human body. One such sensor system is described in U.S. Patent 5,673,692 whose characteristics are incorporated herein by reference in their entirety. However, this particular sensor is not meant as a limitation. Literally any type of bio-sensor or physical sensor generally known to those skilled in the art will find use in the present invention. Further, the

sensor of U.S. Patent 5,673,692 can be modified to include a microphone so that voice of the patient can be transmitted using the system of the present invention.

The sensors are connected to a combination data acquisition module and wireless transceiver which is worn by the patient. This combination sensor package and communication unit is known as the Multi-Variable Patient Monitor, or MVPM. The MVPM is battery-powered. The batteries that power the MVPM can be single use batteries or rechargeable batteries. Further, when the individual is in a mobile state, the batteries of the MVPM can be recharged by plugging them into a car or into normal wall current. This allows the individual to constantly keep batteries charged in the MVPM whether the individual is mobile or in an office.

As noted above, the MVPM is a patient-worn device which allows maximum mobility to the particular patient.

The MVPM has the ability, on a periodic basis, to interrogate bio-sensors worn by the patient and to store physiologic signals from the bio-sensors. On a periodic basic, the MVPM calls into a wireless network and transmits the bio-sensor information to the wireless network. The bio-sensor information then proceeds from the wireless network to the Internet and then to an analysis center or a data warehouse which receives and stores the information for subsequent analysis.

The MVPM also comprises emergency Panic buttons whereby a patient can direct the transceiver portion of the MVPM automatically to call 911 or a designated medical caregiver in the event of a medical emergency.

As noted above, the MVPM is connected to various sensors. Therefore, the MVPM has sensor condition detection circuitry, connected to a lamp and/or message display, which allows a

user to determine that all sensors are operating correctly. When a sensor receives a particular signal which is out of the normal physiologic range for the particular patient, an "alarm" (sound, lamp, or display) is actuated such that the patient can understand that a significant medical event is occurring. Simultaneously with such an alarm, a time-tagged signal is sent to the medical care provider terminal notifying the caregiver of the event.

Thus, when the MVPM is functioning in a data acquisition mode, it receives information from the sensors, performs some limited analysis on that information, and notifies the patient and caregiver of any non-standard conditions.

When the MVPM periodically sends stored signals from the sensors over the network, a unique identifier is encoded with any such data that are sent such that the data can be directly associated with a particular patient.

Once data are received at the Host server, the data are stored with appropriate privacy and security issues dealt with in a manner known to those skilled in the art.

The MVPM also comprises circuitry for self-testing its various sub-systems and sensors and for communicating any trouble shooting information directly to the patient in the event that the sensor becomes dysfunctional. Further, such trouble-shooting data can also be sent in a wireless manner to the central server such that trouble-shooting can take place remotely, or in the alternative, a new MVPM unit can be sent to the patient.

The MVPM also can be preset before giving it to a patient. In addition, and depending upon the biological signals being monitored, "Alarm" variables can be set remotely by the health care provider over the Internet and subsequently via the wireless network and can be based upon the caregiver's knowledge of the condition of the patient. Such remote setting also occurs via the

two-way communication of the transceiver portion of the MVPM.

Communication rates of the WIBMS are optimized to fit wireless telephone communications calling and rate plans and to minimize the cost and air time usage.

Using the WIBMS, the following types of monitoring can take place:

- digitally sampled electrocardiogram
- patient body temperature
- pulse oximetry
- pulse rate
- other physiologic variables, such as blood glucose, respiration, etc.
- various pre set alarm conditions or physiologic variables
- event occurrences per patient action/input.

As also noted above, the MVPM has bi-directional communication capability and has the capability to transmit a "panic" signal over wireless network, to initiate 911 calls, to allow patient-initiated voice-calling over a cellular telephone link, and to allow medical provider voice-calling to the patient over a cellular telephone link.

Other characteristics of the present invention will become apparent to those skilled in the art by review of the detailed description of the invention that follows.

Brief Description of the Figures:

Figure 1 illustrates the Wireless Internet Bio-telemetry System.

Figure 2 illustrates the Multi-Variable Patient Monitoring portion of the WIBMS.

Figure 3 illustrates a front panel drawing of the multi-variable patient monitor portion of the WIBMS.

Detailed Description of the Invention:

As noted above, the present invention is a Wireless Internet Bio-telemetry System comprising a patient monitoring device which is conveniently worn by a patient and which comprises sensors together with a combination network that allows biologic and physical signals to be reviewed and acted upon by a health care provider who is located remotely from the patient. Data from the monitoring system are then sent in a wireless mode over a cellular network to the Internet and then to a data analysis center (Host) for retrieval and review by a medical care provider.

In Figure 1, the Wireless Internet Bio-telemetry System (WIBMS) is illustrated. Patient **10** wears a Multi-Variable Patient Monitor (MVPM) **12**. This MVPM monitors a variety of bio-signals as further noted below. The MVPM **12** has the capability of communicating bi-directionally via voice **14** in much the same manner as a normal cellular telephone. However, in addition, the MVPM sends data **16** on a periodic basis, or in some cases on a continuous, Real-time basis, over a cellular network to the Internet and then to the Host. It also receives requests for data **18** which may be made by a medical care provider over the Internet using wireless or PSTN connections to the Host.

Wireless Network **20** is the normal digital cellular telephone network currently in use. This type of network is not however meant as a limitation. For example, PCS networks and other types of wireless loop networks are also suitable for transmission of the voice and data envisioned by the present invention. It will be apparent to those skilled in the art that such other networks can satisfy the requirements for transmission of voice **14**, data **16**, and request for data **18** to and from patient **10**.

Once physiologic data is transmitted over network **20**, it is then transmitted via an Interworking Function (IWF)® **24** (for example), preferably to the Internet **26** for subsequent retrieval and review by a medical care provider at the medical care provider terminal **28**. In addition, data can be archived (again via the Internet **26)** to a data archiving and distribution facility **30** ("Host"). Data that are archived are stored in a private and secure fashion using techniques known in the art that allow secure transmission and access limitations.

In the event that voice traffic is being transmitted from the patient, a cellular network **20** connects to the public telephone network **22** to communicate with the medical care provider (or 911 operator). Although network **22** will usually be a PSTN, other non-switched connections, such as ISDN, DSL, satellite, and cable modem connections can also be used. Again, in this fashion, the medical care provider can receive voice information from the patient **10** and provide voice feedback to the patient as well. Similarly, the medical care provider terminal**28** can both receive traffic from the WIBMS as well as transmit requests for data and configuration changes to the Host **30**. In turn, the Host **30** communicates these requests to the MVPM **12**, receives data, and provides it back to the caregiver over the Internet **26** and PSTN **22**.All data that are received from the MVPM (and the network) can be archived by the Host **30** so that the data from the specific patient can be monitored over time and so that data can be analyzed for trends that can be used for alarm setting and data collection protocols. All such data are transmitted in an encrypted and possibly non-attributable form with limited access using methods known in the art so that patient privacy and confidentiality is maintained.

In Figure 2, the Multi-Variable Patient Monitor (MVPM) is further illustrated. The MVPM (initially noted as **12** in Figure 1) comprises, without limitation a number of sensors. For

example, blood oxygen saturation level (Sp02) **32**, pulse rate **34**, body temperature **36**, and Electrocardiogram (ECG) **37** can all be measured by sensors associated with the appropriate measurement. Signals from the sensors are picked up and stored by the Data Acquisition Module **42**. This information from the sensors **44** is then sent to the CDMA (although other module types may also be used) telephone module **56** of the MVPM for subsequent transmission.

In addition simply to acquiring data, the Data Acquisition Module **42** also notes any Alarm condition **46** and transmits that information via CDMA module **56** over the Internet **26** to the Host **30** where it can be used to notify a medical care provider terminal **28**. Also, Data Acquisition Module **42** transmits the time of day **48** with any transmission of alarm information or sensor information. As noted earlier, the various alarm conditions can be reconfigured by the health care provider over the internet and the wireless network without any patient interaction.

The CDMA module is, for example, one manufactured by Qualcomm® for use within a cellular telephone. That information, in connection with 3Com QuickConnect® Internet connection software and 3Com Interworking Function® (IWF) device are all used to connect to, for example, the Sprint PCS® digital cellular telephone network. The characteristics of the Qualcomm® CDMA cellular phone module, the 3Com QuickConnect® Internet connection software and the 3Com IWF® device are all incorporated herein by reference in their entirety.

The CDMA module **56** allows for digital cellular communications at 14.4 kbps which is sufficient for the transmission of the bio-sensor information contemplated by the present invention. This is not however meant as a limitation, since faster wireless modulated speeds surely will become available. All of these faster connections will be suitable for transmission of the data and voice of the present invention.

Data that are collected are encrypted to prevent eavesdropping or tampering with any commands. All information and data are Internet Protocol (IP) compatible and contain error checking to insure data accuracy.

The Data Acquisition Module **42** continuously monitors, for example and without limitation, Sp02 **32**, pulse rate **34**, body temperature **36**, and ECG **37**,and transmits that information from the MVPM to the Host over the Internet. Data can be transmitted in real time and/or can be stored and forwarded depending upon the collection protocol ordered by the medical service provider. Similarly, temperature measurement, pulse oximetry, and pulse rate all can be collected and transmitted continuously during various periods of time or can be collected stored and burst transmitted over the wireless network as required.

The Data Acquisition Module contains logic that allows an "Alarm" **45** condition to be transmitted at any time whenever the alarm criteria are fulfilled. Further, any alarm condition can be reset by the health care provider via the Host over the Internet and thence over the wireless network. Any "Alert" **47** signals that, for example, a sensor is turned off, broken, or has become disconnected is used to alert the patient to take appropriate action to replace or repair the sensor. While such information is transmitted by the Data Acquisition Module **42** to the CDMA module **56** and thence to the wireless network, a voice synthesizer contained in the Data Acquisition Module **42** also provides a voice alert via speaker **60** to the patient that a particular Alarm **45** or Alert **47** condition has occurred.

As noted earlier, the patient also has the ability to speed dial 911 **38** as needed. Data Acquisition Module **42** also processes this information and passes it over a voice connection **50** to the CDMA module **56** and thereafter to the Wireless Network **20** for communication.

The patient also has the ability to call the medical care provider on a non-emergency basis. This is accomplished by a dedicated function speed dial "button" **40** on the MVPM. Again, Data Acquisition Module **42** processes voice information **50** and passes that information to the CDMA module **56**.

As noted above, the medical service provider or other organization that is responsible for monitoring and maintaining the MVPM can interrogate the Data Acquisition Module of the MVPM through the Host. A request for information flows from the medical care provider terminal over the Internet to the Host. The Host initiates a voice call to the MVPM which triggers the MVPM to establish a data call back to the host. Alternatively, the Data Acquisition Module can be reconfigured **54** to update communications capabilities, or to change the protocol for monitoring physiologic data and to change or modify alarm limits.

The system of the present invention includes the network and can allow any number of MVPMs. In the same fashion that a cellular telephone has a roaming capability, so does the MVPM, therefore allowing the continual transmitting and updating of physiologic data.

In Figure 3, a front panel for the MVPM is illustrated. The MVPM has a time of day **72,** battery capacity **74** and signal strength **75** indicators which allow the wearer to determine if recharging or battery replacement is required and if the signal strength of the communications channel is adequate to support reliable communications. The panel **70** is dimensioned to be small and unobtrusive so that the wearer will not be disproportionately burdened by carrying the MPVM. The panel has several speed dialing preset buttons that allow emergency calls to 911 **76** to be made and to call the care provider **78** simply by pressing a button. Similarly, if the wearer determines that an "Event" has occurred such as faintness, shortness of breath, irregular

heartbeat, or other symptoms, this event button **80** can be pressed causing data be stored and transmitted for a preset period of time. A power indicator **82**, such as a flashing green LED, is part of the panel so that the user can determine that power is "On." Sensor lamp **86**, such as a yellow LED, is on the panel as well to inform the user when a sensor has potentially become disconnected or has otherwise malfunctioned. An Alarm lamp **84**, such as a red LED, together with an audible signal is also present on the control panel so that the patient can have both a visual and audible warning of any Alarm condition that might exist.

The panel design shown in this Figure 3 is by way of illustration only. It will be apparent to those skilled in the art that other panel designs are possible so long as the information is presented in an easy and usable way for the patient.

As noted above, the communications link between the MVPM and the care provider via the PSTN or the Internet is a bi-directional link. Thus, requests for data from a workstation located at the care provider's facility can be transmitted through the Internet to the Host which contacts the MVPM. Data transfer (real time or stored) can be transferred from the MVPM through the Internet to various data bases for analysis or storage. Data from the MVPM can be transferred in real time to or from the storage site through the Internet to other authorized users such as insurance providers. Alarm information is transferred from the MVPM to the care provider through the Internet. When a sensor malfunctions or becomes disconnected from the wearer, a "sensor off" signal is sent from the MVPM and transferred over the Internet to the medical care provider terminal so that such information is available and so that thecaregiver can know when and if it is repaired. Event occurrences, as described earlier, may also be transferred to the Medical Care Provider through the Host. The medical care provider terminal can transmit

a communication to disarm or reset alarms in the MVPM through the Internet as necessary. Further, protocols relating to when and the type of bio-signal to be measured can be sent from the medical provider over the Internet to the Host which transmits this information to the MVPM. The personal emergency button for use by the user to activate a call to the Medical Care Provider gives voice communication from the MVPM to and from the care provider. Real-time clock resets or any other variations in configuration of the MVPM can be transmitted from the Medical Care Provider over the Internet to the Host which transfers this information to the MVPM using the Internet and the Wireless Network.

A Wireless Internet Bio-telemetry System has now been illustrated. It is important to note that, while a particular wireless protocol was described in the preferred embodiment (i.e., CDMA) this is not meant as a limitation. For example, other protocols for communication in a digital wireless network (such as a GSM or a TDMA network) will be equally suitable for use with the present invention. It is also anticipated that other types of wireless networks will also be suitable such as satellite networks and wireless local loop networks. The requirement is that there be two-way communication with the MVPM and that Internet connectivity flow as part of the communication system to allow interaction between health care provider and the patient through voice and data links using the Internet. It will be apparent to those skilled in the art that other variations in, for example and without limitation, the type of network, the types of sensors, and the configuration of the patient monitor can be accomplished without departing from the scope of the invention as disclosed.